EXHIBIT A

OMB No. 0925-0195
Expiration Date 8/31/2001

Department of Health and Human Services
Public Health Service
Small Business Innovation Research Program
Phase I Grant Application
Follow instructions carefully.

Leave blank — for PHS use only.		
Type	Activity	Number
Review Group		Formerly
Council Board *(Month, year)*		Date Received

1. TITLE OF APPLICATION *(Do not exceed 56 typewriter spaces)*
Development of a Massed Practice Stroke Therapy Device

2. SOLICITATION NO. PHS 98-2

3. PRINCIPAL INVESTIGATOR ☐ New Investigator

3a. NAME *(Last, first, middle)*
Koeneman, James Bryant

3b. DEGREE(S) BSME | MS | PhD

SOC. SECURITY NO. *(Provide on Personal Data Page)*

3d. POSITION TITLE
Senior Bioengineering Consultant

3e. MAILING ADDRESS *(Street, city, state, zip code)*
BTI Consultants
1937 East Broadway
Tempe, AZ 85282

3f. TELEPHONE AND FAX *(Area code, number, and extension)*
TEL: 480-967-1000
FAX: 480-967-4355

BITNET/INTERNET Address:
jbk@btic.com

4. HUMAN SUBJECTS ☐ NO ☒ YES
4a. If "Yes," Exemption no.
IRB approval date: Pending
☐ Full IRB or Expedited Review
4b. Assurance of compliance no.

5. VERTEBRATE ANIMALS ☒ NO ☐ YES
5a. If "Yes," IACUC approval date
5b. Animal welfare assurance no.

6. DATES OF PROJECT PERIOD
From: Nov. 5, 2001 *Through:* April 30, 2002

7. COSTS REQUESTED
7a. Direct Costs: $ 90,000
7b. Total Costs: $ 100,000

8. PERFORMANCE SITES *(Organizations and addresses)*
BTI Consultants
1937 East Broadway Road
Tempe, AZ 85282-1701

Barrows Neurological Institute -
St. Joseph's Hospital
350 West Thomas Road
Phoenix, AZ

9. APPLICANT ORGANIZATION *(Name and address of applicant small business concern)*
BTI Consultants
1937 East Broadway
Tempe, AZ 85282

10. ENTITY IDENTIFICATION NUMBER: 86-0411058
Congressional District: 1

11. SMALL BUSINESS CERTIFICATION
☒ Small Business Concern ☐ Women-owned
☐ Socially and Economically Disadvantaged

12. NOTICE OF PROPRIETARY INFORMATION: The information identified by asterisks(*) on pages ____ of this application constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application, provided that, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

13. DISCLOSURE PERMISSION STATEMENT: If this application does not result in an award, is the Government permitted to disclose the title only of your proposed project, and the name, address, and telephone number of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information or possible investment? ☒ YES ☐ NO

14. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name: Vaughn P. Adams, Jr., P.E., Ph.D.
Title: President and CEO
Address: BTI Consultants
1937 East Broadway
Tempe, AZ 85282

Telephone: 480-967-1000
FAX: 480-967-4355
BITNET/INTERNET Address:
vpa@btic.com

15. PRINCIPAL INVESTIGATOR ASSURANCE: I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PERSON NAMED IN 3a *(In ink. "Per" signature not acceptable.)*
James B Koeneman
DATE: 3/29/01

16. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF PERSON NAMED IN 14 *(In ink. "Per" signature not acceptable.)*
V P Adams
DATE: 3-29-01

Abstract of Research Plan

NAME, ADDRESS, AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION

BTI Consultants
1937 East Broadway Road
Tempe, AZ 85282
480-967-1000

YEAR FIRM FOUNDED	NO. OF EMPLOYEES *(include all affiliates)*
1981	Full time: 13 Part time: 14

TITLE OF APPLICATION

Development of A Massed Practice Stroke Therapy Device

KEY PERSONNEL ENGAGED ON PROJECT

NAME	ORGANIZATION	ROLE ON PROJECT
James B. Koeneman, Ph.D.	BTI Consultants	PI, Biomechanics
Christina Kwasnica, M.D.	Barrows Neurological Inst.	Clinical Requirements and Evaluation
Douglas Wendelboe	BTI Consultants	Firmware Design
Edward Koeneman	BTI Consultants	Electronic Design and Prototype Fabricator
Donald Herring	BTI Consultants	Industrial Design, Human Factors

ABSTRACT OF RESEARCH PLAN: State the application's broad, long-term objectives and specific aims, making reference to the health-relatedness of the project. Describe concisely the research design and methods for achieving these goals and discuss the potential of the research for technological innovation. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. ***Therefore, do not include proprietary or confidential information.*** DO NOT EXCEED 200 WORDS.

Stroke (CVA) is the leading cause of disability in the United States and it is estimated that its prevalence will more than double over the next 50 years. Current stroke therapy is labor-intensive and costly. The United States spends $17 billion taking care of stroke survivors. Recently, concentrated, massed practice therapies have been developed that improve function in CVA patients by reversing the effects of "learned nonuse". The objective of this project is to develop a device that facilitates the administration of massed practice stroke therapy. The long-term objective is to provide a lightweight device for home use that provides motion, biofeedback, and neuromuscular stimulation. Software will be developed that controls the function of the device and monitors patient progress and compliance. A pneumatic artificial muscle will be used to provide physical motion. This artificial muscle has many of the properties of human muscle. It is lightweight, flexible and has spring-like properties. This project will focus on treating wrist extensor weakness, however, the concept applies to all areas affected by motor impairment.

Provide key words (8 maximum) to identify the research or technology.

Stroke therapy, massed practice, EMG biofeedback, neuromuscular stimulation, rehabilitation, pneumatic artificial muscle.

Provide a brief summary of the potential commercial applications of the research.

This device will provide an economical means of administering massed practice stroke therapy. This device has the potential to provide effective treatment for other motor disabilities such as patients with traumatic brain injury, spinal cord injury, and hip fracture.

Budget Justification

Using continuation pages if necessary, describe the specific functions of the personnel and consultants. Read the instructions and justify costs accordingly.

James Koeneman, Ph.D., PI, will coordinate the project and be responsible for the biomechanical design issues and risk analysis. He will spend 30% of his time on the project.

Christina Kwasnica, M.D., will coordinate the clinical input to the design requirements and the clinical evaluation of the device.

Douglas Wendelboe will be responsible for firmware and electronic hardware design. He will spend 30% of his time on this project.

Donald Herring will be responsible for the design of the arm attachments and the human factors and industrial design issues. He will spend 15% of his time on the project.

Edward Koeneman will be responsible for construction and testing of prototypes. He will spend 30% of his time on the project.

Vaughn Adams will chair the Advisory Board and supervise the risk analysis. He will devote 10% of his time to the project.

The Advisory Board consultants are budgeted at $10,000.

Dr. He will consult on neuromuscular stimulation and EMG sensing.
Glen Stranton will consult on manufacturing issues.
Deborah Koeneman will consult on GMP and regulatory issues.
John Koeneman will consult on Phase III implementation.

The expenses at the Barrow Neurological Institute for patient evaluation studies in the last month of the project are budgeted at $10,000.

No fixed fee is requested.

Resources

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. (The research to be performed by the applicant small business concern and its collaborators must be in facilities that are available to and under the control of each party for the conduct of each party's portion of the proposed project.) Indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Include laboratory, clinical, animal, computer, and office facilities at the applicant small business concern and any other performance site listed on the FACE PAGE. Identify support services such as secretarial, machine shop, electronics shop, and the extent to which they will be available to the project. Use continuation page(s) if necessary.

BTI Consultants owns and/or leases approximately 11,000 square feet of office, laboratory and warehouse space. The facility houses offices, meeting rooms, lunch room, two shop areas, microscopy area, library and a computer lab. The library has an extensive collection of safety, human factors, and engineering books and industrial safety standards. All office computers are connected by a Novel Network and all have Internet access through a frame relay line. Receptionist, shipping/receiving, secretarial, facsimile, copying and technician assistance are available to this project.

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

Approximately 1,000 square feet of office and prototype lab space have been exclusively allocated to this project. Video and 35 mm cameras, a large format color printer (36"), a 4x compact disk recorder, and various computer simulation programs and equipment, including AutoCAD, 3D Studio MAX, Photoshop, Illustrator, Character Studio, Speed Razor, Humanoid, Perception Video Capture, and Sound Forge, are available for use.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
James B. Koeneman	Senior Biomechanics Consultant

EDUCATION (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Minnesota, Minneapolis, MN	BSME	1959	Mechanical Engineering
Case Western Reserve University, Cleveland, OH	MS	1966	Bioengineering
Case Western Reserve University, Cleveland, OH	PhD	1970	Structures/Mechanical Design

RESEARCH AND PROFESSIONAL EXPERIENCE

1994 - present	Senior Bioengineering Consultant, BTI Consultants, Tempe, AZ. Assistive Devices, Biomechanics, Development of Composite Materials, Stress Analysis, Failure Analysis.
1994 - 1998	V.P. of Engineering, Orthologic Corporation, Tempe, AZ. Fracture fixation devices, bone growth stimulators.
1984 - 1994	Head of Bioengineering Division, Harrington Arthritis Research Center, Phoenix, AZ. Development of assistive devices, orthopedic implant design and testing, finite element analyses.
1981 - 1983	President, Paulson Medical Devices, Inc., Erie, PA. Development of fracture fixation devices and orthopedic implants.
1974 - 1981	Head of Bioengineering Division, Lord Corporation, Erie, PA. Development and manufacture of orthopedic implants. Composite material development.
1970 - 1974	Bell Telephone Laboratories, Columbus, OH. Development of Piezoelectric switching devices.
1960 - 1964	Reactor Engineer, U.S. Atomic Energy Commission, Argonne, IL.
1959 - 1960	Reactor Engineer, Argonne National Laboratory, Idaho Falls, ID.

PUBLICATIONS

Recipient of 16 patents, co-author of 22 publications and over 115 presentations at technical society meetings. Seven relevant publications listed below:

J.B. Koeneman and J.S. Kaiser, "A Functional Evaluation of the DataHand® Key Entry System User Experience Evaluated By Questionnaire," RESNA, 1994.

J.B. Koeneman and C. Eblen, "A Longitudinal Evaluation of Four-Wheeled Walker: Effects of Experience," Topics in Geriatric Rehabilitation, 8(3)3, 1993.

J.B. Koeneman, "Advanced Materials for Assistive Devices," Topics in Geriatric Rehabilitation, Vol. 8, No. 2, December 1992.

J.B. Koeneman, with others, "A Multi-Dimensional Evaluation of a Four-Wheeled Walker," Assistive Technology, Vol. 4, No. 1, 1992.

J.B. Koeneman, N. Reich, P. Otten, and J. Kaiser, "Clothing for Special Needs; An Information Arena," 10th Annual RESNA Conference, San Jose, CA, 1987.

J.B. Koeneman and M. Phillips, "Composite Materials for Rehabilitation Devices," 10th Annual RESNA Conference, San Jose, CA, 1987.

J.B. Koeneman, "State of the Art of Finite Element Analysis in Orthopaedics," Materials Research Society, Proceedings of Medical Devices and Materials Symposium, 1987.

AWARDS

International Fellow of Biomaterials Science and Engineering; International Union of Societies for Biomaterials Science and Engineering (1999)

Clemson Award for Contributions to the Literature, Society for Biomaterials (1997)

Fellow of Society for Advancement of Material and Process Engineering International (SAMPE) (1992)

Chapter Fellow Award, Society for Advancement of Materials and Process Engineering (SAMPE) (1990)

Engineer of the Year Award, Erie Engineering Society Council (1982)

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Christina M. Kwasnica, M.D.	Director of Brain Injury Rehabilitation

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Arizona, Tucson, AZ	BA	1991	Political Science
Northwestern University Medical School, Chicago, IL	MD	1995	Medicine

POSITIONS

2000-Present Director of Brain Injury Rehabilitation Barrow Neurological Institute, Phoenix, AZ

1999-2000 Clinical Instructor and Cognitive Neurology Fellow, Northwestern University Alzheimer's Disease Center, Departments of Neurology and Physical Medicine and Rehabilitation, Chicago, IL

1995-1999 Resident Physician, Northwestern University Medical School/Rehabilitation Institute of Chicago, Department of Physical Medicine and Rehabilitation, Chicago, IL

PROFESSIONAL AFFILIATIONS

Diplomate, American Board of Physical Medicine and Rehabilitation
Fellow, American Association of Physical Medicine and Rehabilitation
Diplomate, Association of Academic Physiatrists

AWARDS AND HONORS

Seabury Foundation Endowed Research Resident, July 1998-June 1999
NIH National Research Service Award Fellowship, F32 NS10858-01, August 1999-August 2000
Sara Baskin Award for Research Excellence, Rehabilitation Institute of Chicago, May 1999
President's C62nd Annual, 2nd Annual Assembly of the American Academy of Physical Medicine and Rehabilitation, for outstanding paper presentation, "Predictors of Ambulation in Stroke Rehabilitation"

RESEARCH PROJECTS ONGOING OR COMPLETED DURING THE LAST THREE YEARS

Current Predictors of Ambulation in Stroke Rehabilitation with Dr. Richard Harvey, Rehabilitation Institute of Chicago

Pending Unilateral Neglect and the Relationship of Measurements with Function

Prior Bromocriptine in Unilateral Neglect- F32 NS10858-01
NIDRR Stroke Research and Training Center- Rehabilitation Institute of Chicago

PEER REVIEWED PUBLICATIONS

Kwasnica, C.M. and Heinemann, A. "Coping with Traumatic Brain Injury: Representative Case Studies," Archives of Physical Medicine and Rehabilitation, April 1994, pp. 384-389

Grujic, Z., Mapstone, M., Gitelman, D., Weintraub, S., Johnson, N., Hays, A., Kwasnica, C.M., Harvey, R.L., and Mesulam, M. "Dopamine Agonists Reorient Visual Exploration Away from Neglected Hemisphere," Neurology, December 1998

Kwasnica, C.M. "Unilateral Neglect after Right Hemisphere Stroke- a Review of the Syndrome and Management," Critical Reviews in Physical Medicine and Rehabilitation, accepted for publication December 2000

SELECTED RECENT ABSTRACTS AND PRESENTATIONS

Kwasnica, C.M., Harvey, R.L., and Mullarkey, C. "Predictors of Ambulation in Stroke Rehabilitation," Presented at the America Academy of Physical Medicine and Rehabilitation annual meeting, November 2000

Kwasnica, C.M., Cherney, L., and Harvey, R.L. "Unilateral Neglect and Relationships with Functional Outcomes," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November 1998

Kwasnica, C.M., Grujic, Z., Mapstone, M., and Harvey, R.L. "Bromocriptine Effect on Unilateral Visual Neglect After Right Hemisphere Infarct: A Pilot Study," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November 1997

Managing Neglect Syndrome after Stroke: A Complete Experience- Annual Assembly of the American Academy of Physical Medicine and Rehabilitation, November, 1998

Managing Neglect Syndrome after Stroke: A Complete Experience- Annual Multidisciplinary Stroke Course- Rehabilitation Institute of Chicago, April 1999

Pharmacology of Brain Injury- Rehabilitation Institute of Chicago, December 2000

Non-traumatic Brain Injury- Rehabilitation Institute of Chicago, December 2000

Pharmacologic Approaches to Motor Recovery after Stroke- Annual Multidisciplinary Stroke Course- Rehabilitation Institute of Chicago, April 2000

Atypical Dementias- Grand Rounds- Ingalls Hospital- Chicago, IL, April 2000

Neuroplasticity and Rehabilitation- Grand Rounds- Rehabilitation Institute of Chicago, July 2000

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Douglas E. Wendelboe	Software Consultant; President, Penn Microsystems

EDUCATION (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Pennsylvania State University, State College, PA	BS	1972	Electrical Engineering
University of Pennsylvania, Philadelphia, PA	MS	1976	Electrical Engineering

RESEARCH AND PROFESSIONAL EXPERIENCE

1998-Present Software Consultant, BTI Consultants, Tempe, AZ. Design of hardware and software for medical devices

1981-Present President, Penn Microsystems. Consulting on microprocessor-based products. Medical device projects include:

- Hand-held Blood Prothrombin-Time Measuring Device, San Jose, CA, 2000-Present
- Designed and implemented the Automated Calibration and Test System for the Bone Growth Stimulator, Phoenix, AZ, 1999-2000
- Firmware enhancements for an electromagnetic Bone Growth Stimulator, Phoenix, AZ, 1997-1999
- Developed an Automated Active Burn-In System for the Bone Growth Stimulator, Phoenix, AZ, 1996-1997
- Designed and implemented firmware for Nerve Integrity Monitor Instrument, Jacksonville, FL, 1994-1995
- Designed, implemented, and maintained the firmware for a line of Micro-titer Plate Readers, Winooski, VT, 1982-1985
- Designed and implemented the complete firmware for a Pacemaker Systems Analyzer, Winooski, VT, 1980-1981

1977-1981 Senior Associate Engineer, IBM Corp., Essex Junction, VT

1976-1977 Senior Product Engineer, Honeywell Corp., Ft. Washington, PA

1972-1976 Design Verification Software Engineer, UNISYS (Sperry-Univac), Blue Bell, PA

PROFESSIONAL PUBLICATIONS

"Recommended Use of the PL/M Computer Language in Safety-Related Systems," Report for the Nuclear Regulatory Commission, NUREG/CR-6463, June 1996

Co-publisher of the Annual "Arizona High Tech Directory"

Columnist for the "Arizona High Tech Times" newspaper

PROFESSIONAL

IEEE Computers, IEEE Software, IEEE Management, IEEE Biomedical

American Society for Quality

TECHNICAL SKILLS

Languages: Keil C51 w/uVision2, IAR C, PIC-C, 8051, 8x86, 68xx, 68xxx assembler, Microchip PIC, Hitachi H8 assembler, TMS320C54x Algebraic assembler, National Instruments LabWindows/CVI, Microsoft Visual C++, Visual Basic

RTOS: uC/OS-II, QNX, Keil RTX-51, familiarity with VxWorks, Tornado

Microprocessors: Intel 8051, 80251, 8X93x USB, Intel 80x86, 80188, 386EX, 68HC05, 68HC08, 68HC11, 68xxx family, Hitachi 6303, H8S/2134, Microchip PIC16C74, 16C65, ST Micro ST10F167/168

In-Circuit Emulation: Intel ICE 8051, 8085, 80188, 80x86, Nohau EMUL51-PC: 80C552, 89C51RD2, Microchip PIC-Master & others

Peripheral Buses: I^2C, CAN v2.0, USB, Motorola SPI, Dallas Semiconductor interfaces

Design Standards: IS)-9001 Design Quality Standards, FDA (97-4179) Medical Device Quality Systems Standards, FDA 510(k), FDA Pre-Market Approval (PMA)

Bus Boards: PC/104 Bus, STD Bus, VME Bus

Logic: SPICE Simulation, Programmable Logic Compilers

Network: TCP/IP, WATTCP

Database: MS SQL7, Oracle, Informix

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Edward J. Koeneman	Consultant

EDUCATION (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Arizona State University, Tempe, AZ	BSEET	1992	Electronic Engineering
Arizona State University, Tempe, AZ	MT	1994	Electronic Engineering

POSITIONS

1999-Present	BTI Consultants, Consultant.
1997-1999	Adtron Corp., Mesa, Arizona. Product Manager, Data Storage Devices.
1997	PCI Medical, Phoenix, Arizona. Design Engineer, Medical Electronics.
1995-1997	Prescom Electronics, Mesa, Arizona. Chief Engineer, Contract Electronic Design and Manufacturing.
1988-1995	Harrington Arthritis Research Center, Phoenix, Arizona. Lab Coordinator for Orthopaedic Resident Projects, Mechanical Testing.

PEER REVIEWED PUBLICATIONS

Koeneman, E.J., J.A. Lerman, R.J. Haynes, J.B. Koeneman, W. B. Wong, "A Biomechanical Comparison of Gardner-Wells Tongs and Halo Device Used for Cervical Spine Traction," SPINE, Volume 19, Number 21, pp. 2403-2406, 1994.

Koeneman, E.J., N.R. Crawford, A.G.U. Brantley, C.A. Dickman, "An Apparatus Applying Pure Nonconstraining Moments To Spine Segments In Vitro," SPINE, Volume 20, Number 19, pp. 2097-2100, 1995.

SELECTED PRESENTATIONS

Koeneman, E.J., J.A. Lerman, J.E. Maisel, J.B. Koeneman, "Electromyographic Analysis of the Hockey Slapshot," Presented at 1994 Fall Meeting of the Biomedical Engineering Society.

AWARDS AND HONORS

IEEE Outstanding Student Achievement Award, 1993

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Donald E. Herring	Senior Industrial Design Consultant

EDUCATION (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
American University, Washington, DC	BA	1967	Govt. and Public Admin.
Arizona State University, Tempe, AZ	BS	1982	Product Design
Arizona State University, Tempe, AZ	MSD	1993	Human Factors and Design

PROFESSIONAL EXPERIENCE

2001-Present	Senior Industrial Design Consultant, BTI Consultants, Tempe, Arizona
1998-Present	Assistant Professor, Arizona State University, Tempe, Arizona
1997-1999	Proprietor, Redfish Design, Phoenix, Arizona
1994-1997	Assistant Professor, Purdue University, West Lafayette, Indiana
1992-1994	Exhibit and Industrial Designer, Sunbelt Scenic Studios, Inc., Tempe, Arizona
1991-1992	Exhibit Designer, Giltspur Exhibits, Phoenix, Arizona
1982-1989	Senior Project Designer, Mattel Toys, Hawthorne, California
1975	Arizona Real Estate Sales and Brokerage, Phoenix, Arizona
1973	Specialist, United States Treasury Department, Washington, D.C.
1972	Foreman, Athens Paint & Drywall Company, Alexandria, Virginia
1968	OJT Contract Writer, Washington Urban League, Washington, D.C.
1968	Capitol Policeman, United States Capitol Building, Washington, D.C.

PRINCIPAL PROFESSIONAL PUBLICATIONS AND PRESENTATIONS

"Children's Computer Human Factors and Seating Recommendations" (For Our Greatest Future Resource), Natural Resources, 1995 IDSA Design Education Conference Proceedings, Santa Fe, New Mexico, September 1995

"Twenty Years Later: What Are the 11982 Graduates of an Industrial Design Program Doing in the New Millennium?," Gumbo, 2000 IDSA Design Education Conference Proceedings, New Orleans, Louisiana, September 2000

MEMBERSHIPS IN SCIENTIFIC AND PROFESSIONAL SOCIETIES

Human Factors and Ergonomics Society of America
Arizona Chapter Member of the Human Factors and Ergonomics Society of America
Industrial Design Society of America (IDSA)
The Arizona IDSA Chapter Secretary (Founding member and officer)
The Indiana IDSA Chapter Secretary/Treasurer (Resigned, April, 1997)

PATENTS

U.S. Patent 4,787,876 - Toy Musical Play Set, 11/29/88, assigned
U.S. Patent 4,673,373 - Transformable Toy Block, 6/16/87, assigned
U.S. Patent 4,645,471 - Busy Ball Child's Toy, 3/7/85, assigned

AWARDS, SCHOLARSHIPS AND HONOR SOCIETIES

Netherlands Toy of the Year Award to Disney Pots and Pans Band based on Originality, Safety and Suitability, 1988

Second Place Award ($2,000.00) in Mattel's Toy of the Year Contest for the Invention and Development of the Double Dooz Transformers Toy Line, 1986

Nominated for the Mattel Toys Presidents Award for Leading a "Brainstorming Event" with 40 Participants Producing 100 Product Concepts for Presentation in Ten Days, 1985

Mattel $2000.00 Discretionary Award for "The First Innovative Preschool Product Line to Come out of Mattel in Eight Years," 1985

Arizona State University Outstanding Senior Industrial Design, 1982

Honorable Mention ($250.00) in Mattel Toy Design Contest, 1982

Awarded Internship at Mattel Toys, 1982

Phi Kappa Phi National Honor Society, 1982

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Vaughn P. Adams, Jr., Ph.D.	Senior Consulting Engineer

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Arizona State University, Tempe, AZ	BS	1964	Engineering Design
Arizona State University, Tempe, AZ	MS	1970	Human Factors Engineering
Texas A & M University, College Station, TX	PhD	1975	Safety Engineering

CONSULTING AND PROFESSIONAL EXPERIENCE

1980 - present Senior Consulting Engineer, President, C.E.O., BTI Consultants, Tempe, AZ. Human Factors Engineering, Systems and Product Design, Man/Machine System Integration, Product and Mechanical Design (including Defect and Patent Analysis), Consumer Product Risk Analysis, Hazard Quantification in Product and Systems Design, Systems Safety Engineering, System Safety Quantification Techniques such as Failure Mode and Effects Analysis, Fault Tree Analysis, Hazard Analysis, Biostereometric Applications to Physical Anthropometry, Forensic Engineering, Occupational Health and Safety Engineering.

1973 - 1980 Professor, Chairman, Department of Design Science, Arizona State University, Tempe, AZ.

1972 - 1973 Sabbatical to Texas A & M University, College Station, TX.

1964 - 1972 Lecturer to Assistant Professor, Arizona State University, Tempe, AZ.

PROFESSIONAL SOCIETIES

Society of Automotive Engineers (Member)
American Society of Engineering Education (Member)
Society of Manufacturing Engineers (Senior Member)
Society of American Value Engineers (Member)
Human Factors Society (Member)
American Institute of Industrial Engineers (Member)
American Society of Safety Engineers (Professional Member)
National Academy of Forensic Engineers (Fellow) #68F
System Safety Society (Member)
National Society of Professional Engineers (Member)
Society of Professional Engineers - Arizona (Member)
Society of Professional Engineers - Texas (Member)
Arizona Council of Engineering and Scientific Associations (Member)
American Society of Testing and Materials (Member)
American National Standards Institute (Member)
American Society of Agricultural Engineers (Member)
Human Factors and Ergonomics Society (Member)

HONORS

ASEE-NASA Faculty Research Fellowship, Stanford University, Ames Research Center (1980)
ASEE-NASA Faculty Research Fellowship, University of Houston, Johnson Space Center (1976-77)
Alpha Pi Mu (National Industrial Engineering Honor Society) Texas A & M University (1973)
Psi Chi (National Psychology Honor Society) Texas A & M University (1973)
ASEE-NASA Summer Faculty Fellowship Program in Systems Design, Stanford University (1968)
Graduation with Distinction, Arizona State University, College of Engineering Sciences (1964)

Koeneman, James Bryant

RESEARCH PLAN

A. SPECIFIC AIMS

The overall purpose of this project is to improve the restoration of physical function of stroke patients by incorporating into one device, three treatment modalities (massed therapy, neuromuscular stimulation, and biofeedback) that individually are successful in treating stroke patients. The device will provide cost effective therapy by supplying more information to the physician and therapist while reducing the amount of patient contact time. The device will be adaptable to accommodate the changing paradigm of cardiovascular accident or stroke (CVA) rehabilitation service delivery and to assist in studies designed to refine therapy protocols.

The specific aims of this proposal are:

1. Define the specific clinical information and display format that supports effective physician and therapist evaluation.
2. Write firmware to control, record, and display device function.
3. Design and fabricate a small, lightweight, portable control and patient-monitoring module.
4. Optimize the pneumatic system to provide a power source that allows therapy to continue during activities of daily living.
5. Fabricate and supply a prototype device for clinical testing.

B. SIGNIFICANCE

Many people have movement disabilities caused by disease or injury. Among the causes are CVA, traumatic brain injury, multiple sclerosis, spinal cord injury and Parkinson's disease. This project focuses on stroke. However, the results will have application to other causes of movement disability. Stroke is the leading cause of disability in the United States with at least 700,000 new cases each year [1, 2, 3]. Over half of these people have residual physical disability. Current stroke therapy is labor-intensive and costly. Often insurance does not cover the cost of full therapy. One estimate is that the United States spends $30 billion a year to take care of stroke survivors. Seventeen billion dollars of this is direct medical cost and thirteen billion is indirect cost due to lost productivity [3]. Another estimate is that the total direct and indirect costs of stroke are $43.3 billion per year [3]. The number of strokes is projected to increase due to the increase in the over 50 "baby boom" population. Also, new pharmaceutical treatments for stroke are projected to increase the number of patients surviving a stroke and increase the percentage of stroke victims requiring rehabilitation. A recent estimate is that the prevalence of stroke will more than double over the next 50 years [2].

Historically, therapy for CVA patients has concentrated on helping a patient adapt to their disability. This methodology is reinforced by the reduction in covered rehabilitation services. It has been shown that this treatment leads to "learned nonuse" that hinders the restoration of available function [2]. Animal studies suggest that learned nonuse is established by the initial organic damage. A patient is

punished for trying to use the affected limb and is rewarded for using other parts of the body. Over time, healing of the organic damage occurs but the suppression of use learned in the acute phase remains in force [4]. Recently, concentrated therapies have been developed that improve function in CVA patients by reversing the effects of "learned nonuse" [4]. As discussed by Taub [4], many of the therapies that have been shown to be effective in restoring function involve massed practice. Physical therapy training techniques were used by Bach-y-Rita [5, 6] and Franz, Scheetz, and Wilson [7]. Significant improvement in limb function was obtained in chronic CVA patients. Training techniques based on electromyography (EMG) biofeedback improved motor ability of chronic CVA patients in studies by Wolf [8, 9], Basmajian [10, 11], and Balliet [12]. Repetitive concentrated practice produced large therapeutic effects for lower limb function [13, 14, 15]. Taub has thoroughly studied Constraint-Induced (CI) Movement Therapy [2, 32]. His group has shown positive results in controlled randomized studies [16]. Some of these experiments compared several massed therapy techniques and all showed very large increases in limb use over the treatment period.

Two very sophisticated robot systems are being developed for treatment and evaluation of CVA patients [1, 17]. These devices have shown some effectiveness in treatment of CVA patients and have developed very useful data for understanding recovery mechanisms. However, the current cost of these systems preclude their widespread clinical use [18].

Studies show that EMG triggered neuromuscular electrical stimulation is effective in restoring function to CVA patients [26, 27, 28, 29]. However, the discomfort of surface neuromuscular stimulation significantly limits the clinical implementation of this modality for persons with hemiplegia [34]. Low-intensity neurostimulation (stimulation that increases a patient's voluntary range of motion without producing any visible movement at rest) also is effective [28]. This level of stimulation is much more tolerable. Although gross muscle contraction is not produced by low-intensity stimulation, voluntary contraction might be more functional since the flexor/extensor activity of the extremity is better balanced [28]. Low-intensity electrical stimulation has effects similar to functional electrical stimulation except for the lack of motion proprioception. The purpose of the device used in our program is to provide this information with passive motion and combine it with EMG stimulated low-intensity electrical stimulation.

EMG biofeedback treatment of stroke patients has shown some success [30, 31, 12, 8]. This treatment uses surface electrodes to capture the electrical activity of a selected muscle group. An electronic unit converts the signals into visual or audio information for the patient. This information is used by the patient to augment or decrease muscle activity.

A device that has a venerable history in supplying motion to assistive devices is the pneumatic artificial muscle. The artificial muscle exhibits many of the properties of human muscle. The device consists of an expandable internal bladder, e.g., a rubber tube, surrounded by a braided shell. When the internal bladder is pressurized, it expands radially against the braided shell. The pressure on the inside of the braid causes it to contract. Braided finger traps used to hold fingers on therapy devices contract radially when pulled. The air muscle works in the same manner only in the opposite direction, i.e., increasing the diameter causes it to shorten. Like human muscle, the device has spring-

like characteristics, is flexible, and is lightweight. The force-deflection characteristics can be made similar to those of human muscle. This type of device was first used in the 1950s for powered braces [19, 20]. Pressurized air canisters or accumulators that are recharged by air compressors supply air. A major advantage of the air muscle is that it is flexible and can be easily adapted to address the specific loss of function exhibited by a patient. Many refer to this type of device as the McKibben Artificial Muscle. The device has three times the pull force of an air piston of the same cross sectional area. The potential of this device is because it is low cost, lightweight, has a low profile, and has low noise operation. It has not been used extensively because it has been applied in the wrong applications and lack of engineering in critical areas. Research on the application of the air muscle has been revived by the University of Washington [21, 22, 23, 24, 25]. The Shadow Organization in England uses the air muscle to operate biped and multiped robots [33].

The labor-intensive and long treatment times of massed practice make effective rehabilitation expensive. A promising approach to providing a lightweight, low-cost stroke therapy device is a system that synergistically combines three modes of treatment that individually have been shown to be effective (massed practice, electrical neuromuscular stimulation, and biofeedback). We have constructed a laboratory-based prototype of an air muscle powered therapy device that has the adaptability to be used in current treatment modalities and also in the refinement of rehabilitation methods. We attached an artificial muscle between the proximal forearm and a hook on the proximal-dorsal region of the hand. A data acquisition board (Data Translation) and software (LabTech Notebook) were used with a Pentium computer to control an air valve to the muscle and record wrist extensor EMG and wrist position. Images Company, Staten Island, NY, supplied the wrist position sensor. The air tank supplying the muscle was kept at pressure by a compressor. The PC-based system is useful for the development of control and recording strategies. The EMG sensor feeds back information to the patient to reinforce when wrist extensors are active. The EMG signal can also be used to trigger passive motion using the artificial muscle and to provide neuromuscular stimulation. The purpose of this proposal is to transform this PC-based prototype into a self-contained patient-wearable device that records and later displays patient performance.

C. RELEVANT EXPERIENCE

The principal investigator for this development project is Dr. James Koeneman. Dr. Christina Kwasnica is the clinical co-investigator. Douglas Wendelboe and Edward Koeneman are the engineering co-investigators. Dr. Koeneman is responsible for coordination of the project and also for the design, analysis, and characterization of the artificial muscle. Doug Wendelboe is responsible for electronic hardware and firmware design. Ed Koeneman is responsible for fabrication and testing of the prototypes. Don Herring is responsible for human factors considerations and industrial design. Dr. Vaughn Adams will coordinate project evaluation by chairing the Advisory Board and will provide system safety guidance. The qualifications of the investigators are listed below.

Koeneman, James Bryant

Principal Investigator

Dr. Koeneman has over 25 years experience in bioengineering and biomechanics research and development. He started the bioengineering division of a private company. He also was the Vice President of Engineering for a publicly held company that manufactured fracture-healing devices. He managed the Assistive Devices Program at the Harrington Arthritis Research Center. He was elected a Fellow of the Society for the Advancement of Materials and Processing Engineers (SAMPE), received the Clemson Award for contributions to literature from the Society for Biomaterials for his work on the application of composite materials to medical devices, and was elected an International Fellow of Biomaterials Science and Engineering. He has performed analysis and testing of products for many medical device companies. He has 16 patents on medical devices.

Co-Investigators

Dr. Kwasnica is the Director of Brain Injury Rehabilitation at the Barrow Neurological Institute in Phoenix, AZ. The Barrows Institute is part of St. Joseph's Hospital and Medical Center and is well known for its neurological treatment and research. Dr. Kwasnica has been involved in stroke and traumatic brain injury research at the Rehabilitation Institute of Chicago and at the Barrows Institute. She is a Diplomate of the American Board of Physical Medicine and Rehabilitation, the Association of Academic Physiatrists, and a Fellow in the American Association of Physical Medicine and Rehabilitation.

Doug Wendelboe has over 25 years experience with software, firmware, and embedded circuit design. He has developed numerous innovative and well-documented firmware controlled systems for medical devices in accordance with FDA Design Control Procedures. His systems used sensor measurements to control device performance. They included internal calibrations and stored clinical performance for later review by physicians. Don Herring is an experienced Industrial Designer and is currently doing research and teaching classes in a joint program between the Departments of Bioengineering and Industrial Design at Arizona State University (ASU). He is experienced in Human Factors and Person-Machine research. Ed Koeneman has a Master's Degree in Electrical Engineering Technology from ASU and has been testing medical devices and assisting orthopaedic residents with research projects for over 10 years. He developed a telemetry surface EMG system for one of the projects. Dr. Vaughn Adams, the president of BTI Consultants, has over 35 years experience in design, human factors, and system safety engineering. He will chair the advisory board and also consult on the design to insure that system safety is considered during the total design process.

D. EXPERIMENTAL DESIGN AND METHODS

This design project is being done in accordance with Design Control Procedures established by the Food and Drug Administration (FDA). Important parts of Design Control Procedures are to: establish **design requirements**, document a **project plan**, keep a design history file, develop **design specifications** that meet the design requirements, **verify and validate** the design, and have design

reviews at the end of specified design stages. Our PC-driven prototype device will be the starting point for the development program.

Design Requirements

Based on discussions with clinicians and a review of the stroke therapy literature, the need was identified for a simple, low-cost device that could provide massed therapy without requiring continuous therapist attention. Preliminary design brainstorming suggested that the device should incorporate two other effective modalities: biofeedback and electrical neuromuscular stimulation. The Design Characteristics for this design are shown in Table I. During Phase I, these Characteristics will be translated into more quantitative Design Requirements. The Advisory Board that consists of experienced engineers and clinicians will approve the final Design Requirements.

TABLE I: DESIGN CHARACTERISTICS

- The device will provide massed practice, low level neuromuscular stimulation, and EMG biofeedback.
- The device will be sufficiently lightweight so that the patient is comfortable using it for long periods of time.
- Patient compliance will be recorded and available for display at therapist follow-up visits.
- Patient function history will be recorded and available for display at therapist follow-up visits.
- The patient will be able to perform activities of daily living while wearing the device.
- Human Factors considerations will be emphasized during the design process to assure ease of use, patient comfort, and patient compliance.
- A formal Risk Analysis will be prepared during the design process.
- The reliability and maintainability of the device will be considered in the design. The final design will be evaluated for robustness and maintainability.
- The device will be developed under the guidance of Medical Device Design Control Procedures.

Design Specifications

A device to treat wrist extensor weakness was selected as the first application. The PC-based prototype demonstrates that a lightweight air muscle actuated device can be made that incorporates EMG sensing, neuromuscular stimulation, and joint position sensing. During Phase I the functions performed by the general-purpose data acquisition and control software will be translated into specific firmware for a microprocessor that will be worn by the patient. The firmware will be written in blocks with verification of the functioning of each block determined during the writing of the code. All code will be written in accordance with the FDA guidelines for embedded firmware. The code will be fully documented and verified.

The circuitry for the EMG sensor, position sensor, local display, and neuromuscular stimulator will be redesigned and incorporated into one compact unit. The effect of electromagnetic radiation on the functioning of this device will be considered and the radiation generated by the device that could affect other devices will be measured. The design will be completely documented. Once a final design is completed, all specifications and drawings will be approved according to the Document Control System and any changes documented by change orders.

The device will provide the clinician flexibility on treating an individual patient. A basic case would be to have the sequence of events controlled as follows. The patient is instructed to try to extend the wrist when a beep is heard. The EMG sensor and the position sensor are monitored. If an EMG signal is present but no motion occurs, the neuromuscular stimulator and the air muscle are stimulated. If motion is also detected, we will wait until motion has stopped and then trigger the air muscle and apply neuromuscular stimulation. If neither motion nor an EMG signal is sensed, we will wait a period of time, say five seconds, and then trigger the air muscle and neuromuscular stimulation. Full extension will be held for about five seconds and then released. After the displacement has returned to the normal flexion position, we will wait another five seconds, then provide a beep, and the cycle starts all over. The clinician will be provided with basic sequences and triggering modes to choose from and also given the ability to custom design a treatment sequence.

Device attachments, biofeedback, and clinician display will be developed with significant Industrial Design and Human Factors input and review. Based on work with the prototype construction, a rendering of the final configuration of the device is shown in Figures 1 and 2.

Project Plan

Figure 3 is a Gantt chart of the Phase I tasks. The detail specifications of the firmware will be developed in the first month and code written and tested during the rest of the grant period. Selection of hardware components and circuit design begins at the start of the project and continues for four months. Fabrication of prototype boards begins after two and a half months and continues to the end of month five. Selection of suppliers for braid and rubber tubing and finalization of material specifications will be completed by the end of the first month. Mechanical performance of muscle designs will be measured in months two through five. Design of our own surface EMG sensor circuit and electrical stimulating circuit will begin at the start of the project and continue though the end of month five. The characterization of the sensor output will be done in month five. The final selection of the wrist position sensor model will be done in the first month and calibration completed in the second month. Hazard identification and risk analysis will be continuous through all design stages while the final hazards report will be written in month six. The assembled mobile prototype will be completed in the sixth month and tried on subjects with normal muscle function. Once the device performance has been evaluated, the device will be placed on CVA patients with wrist extensor weakness. Comfort and ease of use will be assessed in month six. During the final two months of the project, the final report and Phase II application will be written.

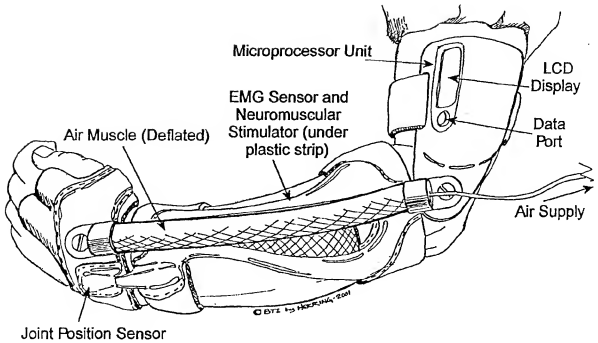

Figure 1 - Flexed Position

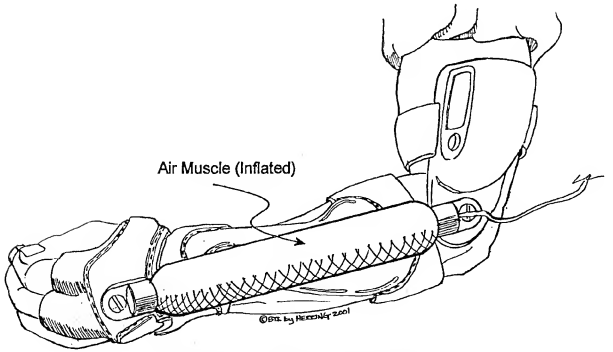

Figure 2 - Extended Position

EXHIBIT A
FIGURE 3
GANTT CHART - PHASE I TASKS

ID	Task Name	Duration	Qtr 4, 2001			Qtr 1, 2002			Qtr 2, 2002	
			Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
1	Detail Firmware Specs	20 days								
2	Write Firmware Code	98 days								
3	Hardware Design	76 days								
4	Hardware Fabrication	54 days								
5	Artif. Muscle Material Sel	22 days								
6	Muscle Characterization	95 days								
7	Pneumatic Circuit Design	110 days								
8	EMG Sensor Charact.	110 days								
9	Wrist Position Sensor Char	22 days								
10	Attachment Optimization	66 days								
11	Risk Analysis	122 days								
12	Subject Evaluation	22 days								
13	Final Rept & Phase II Appl	42 days								

In Phase II a controlled randomized clinical trial will be designed and implemented. CVA patients with chronic motor deficit will be treated with massed practice using this device and the restoration of their motor function will be compared to a similar patient group that undergoes the current standard Barrows CVA therapy. Phase II will also refine manufacturing methods.

Verification and Validation

A Failure Modes and Effects Analysis (FMEA) will be completed by the end of Phase I. This FMEA report is the synthesis of all of the design, testing, and information received during Phase I. All components and how they might fail are considered. Failure modes include the method of securement as well as physical failure of the device. The effects will examine the potential for injury to the patient. To do this analysis, the design during normal patient treatment and under foreseeable misuse must be included. This method establishes a matrix which relates system components to the applicable hazards, effects, severity, frequency, criticality, detection methods, and methods of compensation.

The feasibility of the device developed in Phase I will be evaluated by the criteria listed in Table II. The method of evaluation used to evaluate each is also listed.

TABLE II
PHASE I FEASIBILITY EVALUATION

Characteristic to be Evaluated	*Method of Evaluation*	*Criteria for Feasibility*
Safely control wrist motion	Risk Analysis; quantification of wrist function Range of Motion (ROM)	Risk is determined to be reasonable and acceptable. ROM from 90° flexion to 60° extension for a flaccid wrist
Monitor, record, display, and provide biofeedback of wrist motion and surface EMG signals from wrist extensors	Observation and final evaluation of functioning of the device. Inspection of calibration curves for EMG and wrist position sensors	Verification testing shows the device met the design requirements
Apply comfortable neuromuscular stimulation	Questionnaire administered to subjects	No evaluation greater than mildly uncomfortable
The device is portable and allows activities of daily living during treatment	Questionnaire administered to subjects	Response indicates subjects have mobility during treatment

E. HUMAN SUBJECTS

The use of the device on human test subjects and patients will occur in the final month of the project.

1. Involvement of human subjects: In the final month of the program the device that is developed will be tried on personnel involved in the development of the project. In addition, one or two patients that have wrist extensor weakness will be recruited to try the device in the clinic. An exclusion will be patients with spastic extensors. Clinicians will evaluate fit and comfort and the subjects will be given a questionnaire to complete.
2. Human Research Material: No human specimens or records will be used or recorded except for the response of test subjects to the device.
3. Recruitment of Subjects: Personnel involved with the development of the device will be the first subjects. Clinicians at Barrow Neurological Institute will recruit one or two CVA patients with wrist extensor weakness. This study will be submitted to the Barrows Institute Review Board (IRB). The purpose of the device and any risks involved by use of the device will be explained to the subjects and they will be required to sign a patient consent form that was approved by the IRB.
4. Risks: All hazards associated with use of the device will be identified in the Risk Analysis.
5. Minimization of Risk: Means of controlling the hazards identified in the Risk Analysis will be incorporated into the device design.
6. Reasonableness of Risk: The reasonableness of the risk in relation to the anticipated increase in function will be evaluated in the Risk Analysis.
7. FDA Approval: It is our opinion that this device is not a significant risk device. We will submit the protocol, a description of the device, a patient consent form, and an evaluation of the hazards involved in use of the device and how we are controlling these hazards to the Barrows IRB. If the IRB agrees with us that the device is not a significant risk, then an Investigational Device Exemption (IDE) from the FDA is not required.

F. VERTEBRATE ANIMALS

Not applicable.

G. CONSULTANTS

An Advisory Board for the project will provide advice and guidance on clinical issues, engineering, and product development. The Advisory Board will also approve the Design Requirements. The Advisory Board chair will be Dr. Vaughn Adams and the membership is:

- Dr. Christina Kwasnica, the clinical co-investigator on this project. Dr. Kwasnica's experience and research interests are shown elsewhere in this proposal.

- Dr. Jiping He, an Associate Professor of Bioengineering at Arizona State University. Dr. He is Director of the National Science Foundation Neuromuscular Control Laboratory at ASU and has extensive experience with neuromuscular stimulation and control. He will consult on neurostimulation and EMG sensing and control issues.
- Deborah Koeneman has an MS degree in Bioengineering from ASU. She has worked for the Food and Drug Administration in regulation of Medical Devices. She currently is Director of Regulatory Affairs for OrthoLogic Corporation. She will consult on clinical trial, regulatory, and quality assurance issues.
- Glen Stranton, a manufacturing consultant in Phoenix, will consult on manufacturability issues. Glen has over 17 years experience managing manufacturing operations, many of them involving medical devices.
- Don Herring, an Assistant Professor of Industrial Design at ASU, will consult on human factors, industrial design, and attachment design.
- John Koeneman has a Bachelors Degree from MIT and an MBA from Harvard Business School. He recently retired from the investment banking firm he founded. He will consult on methods of achieving Phase III goals.

H. CONTRACTUAL ARRANGEMENTS

Not applicable for Phase I.

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Checklist

TYPE OF APPLICATION *(Check appropriate box[es].)*

[X] NEW application. *(This application is being submitted to the Public Health Service for the first time.)*

[ ] REVISION of previously-submitted application number _____
(This application replaces a prior unfunded version of a new application.)

[ ] CHANGE of Principal Investigator *(If applicable)*
Name of former Principal Investigator _____

1. ASSURANCES/CERTIFICATIONS

The assurances/certifications set forth below are made and verified by the signature of the OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (small business concern) on the FACE PAGE of the application. Descriptions of individual assurances/certifications are found in application instructions under "Checklist." If unable to certify compliance with any item, provide an explanation and place it after this page.

• Human Subjects; • Vertebrate Animals; • Debarment and Suspension; • Drug-Free Workplace; • Delinquent Federal Debt; • Research Misconduct; • Civil Rights (Form HHS 690); • Handicapped Individuals (Form HHS 690); • Age Discrimination (Form HHS 690).

2. PROGRAM INCOME *(See discussion in application instructions under "Checklist.")*

All applications must indicate *(Yes or No)* whether program income is anticipated during the period for which grant support is requested.

[X] No [ ] Yes *(If "Yes," use the format below to reflect the amount and source(s) of anticipated program income.)*

Budget Period	Anticipated Amount	Source(s)

3. INDIRECT COSTS *(See discussion in application instructions under "Checklist.")*

Insert the rate, if known. If the applicant organization does not have a currently negotiated rate with the Department of Health and Human Services (DHHS) or another Federal agency, it must estimate the amount of indirect costs allocable (applicable) to the proposed Phase I project. That amount should be inserted in the space provided below. The applicant organization should also be prepared to furnish financial documentation to support the estimated amount, if requested by the Public Health Service. An applicant organization may elect to waive indirect costs if it so desires.

[ ] DHHS agreement, dated: _____. _____ % salary and wages or _____ % Total Direct Costs.

[ ] No DHHS agreement, but rate established with _____, dated: _____

[ ] Rate negotiation pending with the National Institutes of Health.

[X] Indirect costs allocable (applicable) to this Phase I project are estimated to be $ 10,000

[ ] No indirect costs requested.

4. SMOKE-FREE WORKPLACE

Does your organization currently provide a smoke-free workplace and/or promote the non-use of tobacco products or have plans to do so?

[X] Yes [ ] No *(The response to this question has no impact on the review or funding of this application.)*

EXHIBIT A

ARIZONA STATE UNIVERSITY

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BIOENGINEERING
BIOLOGY
EXERCISE SCIENCE
PHYSICAL ANTHROPOLOGY

March 27, 2001

Dear Dr. Koeneman,

The proposed project is exciting and the final product will be a valuable addition to the needed rehabilitation devices to help neurologically disadvantaged individuals regain motor function.

I am very glad to have this opportunity to work with you and your staff, as well as other experts, to develop a new system for motor disorder rehabilitation. I have been working on rehabilitation related research and teaching for the last ten years. Through the years I have accumulated expertise on neuromuscular control of posture and movement, spasticity evaluation and treatment, various neurological disorders such as multiple sclerosis, stroke, cerebral palsy, spinal cord injury, and Parkinson's disease, EMG recording and analysis, electrical stimulation, pneumatic muscles, and related instrumentation design and usage. I believe my knowledge can contribute significantly to the development of the system proposed in the application.

I would be happy to serve as a consultant in the Advisory Board. Please do not hesitate to let me know if you need any additional information.

Sincerely,

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